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EXAMINER	
PANDE, SUCHIRA	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
08/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,293	OONO ET AL.	
	Examiner	Art Unit	
	SUCHIRA PANDE	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/30/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 10, 2009 has been entered.

Claim Status

2. Applicant has cancelled claims 1-5, 7-11; amended claim 6 and added new claims 12 and 13. Currently claims 6, 12 and 13 are pending and will be examined in this action.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on June 30, 2009 was filed after the mailing date of the Final Rejection on September 10, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

4.

Response to Arguments

Re 103 rejection of claim 6 over Nova et al.; Akram et al.; Geng et al. and Hirabayashi et al.

5. Applicant's arguments filed June 10, 2009 have been fully considered but they are not persuasive. Applicant has amended the claim 6 to add the limitation to

step (ii) indirect binding that is mediated by a by a substrate selected from the group consisting of cellulose vinyl acetate, α-cyanoacrylate, silicon denatured polymer, epoxy resin, and calcium sulfate.

Applicant argues following:

1) that Geng et al. do not teach direct binding

2) that Geng et al. do teach indirect binding that is mediated by a by a substrate selected from the group consisting of cellulose vinyl acetate, α-cyanoacrylate, silicon denatured polymer, epoxy resin, and calcium sulfate.

Examiner's disagrees and provides following response: As previously pointed out by Examiner Applicant has not defined direct or indirect binding in the specification. Hence any binding taught by the prior art inherently will be either by direct or indirect binding. Thus any art that teaches binding will read upon the currently recited claims. Thus

1) Geng et al. do teach direct binding

2) Geng et al. also teach indirect binding.

Furthermore as pointed out earlier Geng et al. teaches wherein a substrate mediates binding of the protein to the LSI (see page 295 section 2.2 where silica based supports are taught that mediates binding of the protein). Geng et al. also teaches wherein the substrate is silicon denatured polymer (see page 295 section 2.2 where APS silica, NAS-PAA silica is taught as silicon denatured polymer). Therefore by

teaching silicon denatured polymer as the substrate that mediates binding of the protein Geng et al teach binding mediated by a substrate selected from the group consisting of cellulose vinyl acetate, α-cyanoacrylate, silicon denatured polymer, epoxy resin, and calcium sulfate.

Finally Applicant state that "the present invention accomplishes labeling of a "protein that has a sugar chain" by----- (ii) indirect binding mediated by a substrate which cannot be a lectin." This argument and the supporting documents supplied in Exhibit A-C are not being considered further because Applicant is arguing limitations that are not recited in instant claims. Instant claim does not recite---" indirect binding mediated by a substrate "**which cannot be a lectin**".

Thus all elements of currently amended claim 6 are taught by cited art. Hence rejection of claim 6 over previously cited art is still valid and is being maintained.

Claim Interpretation

6. In the instant claims "labeling" is equivalent of binding the protein to a chip. Applicant has not defined "how to bind protein via sugar chain" and "how to record specific information characteristic of the sugar chain". Therefore Examiner is interpreting that any process where protein is bound to a chip will anticipate this invention. For prior art search purposes, Examiner is broadly interpreting labeling to mean binding of protein or peptide (tryptic glycopeptides or glycopeptide fragments) via a sugar chain (any oligosaccharide that is present on glycoproteins) to a substrate (such as immobilized lectins from different sources).

7. Since Applicant has not defined direct or indirect binding in the specification. Therefore Examiner is broadly interpreting that any binding taught by the prior art inherently will be either by direct or indirect binding. Thus any art that teaches binding will read upon the currently recited claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 6, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al (U.S. Patent 5,741,462—previously cited) in view of Akram et al (U.S. Patent 6,250,192—previously cited) ; Geng et al. (2001) J. of Chromatography B. 752: pp 293-306—previously cited and further in view of Hirabayashi et al. (2001) Proteomics 1: 295-303—previously cited).

Regarding claim 6, Nova et al. teaches a method for producing a labeled protein (see abstract), wherein the method comprises binding a protein that has a sugar chain to a large scale integrated circuit (see column 29, line 45 to column 30, line 14, where antibodies (antibodies are proteins that have sugar chains) are bound to the integrated circuit, and recording specific information that is characteristic of the peptide (see column 29, lines 50-55 where each antibody "is given a specific identification tag") on the large scale integrated circuit (see columns 29 and 30).

Regarding claim 6, Nova does not teach the use of integrated circuits with 320 million bits of memory (equivalent to 40 million bytes or 40 megabytes of memory).

Regarding claim 6, Akram teaches the use of RFID integrated circuits with a capacity of 64 megabytes (see column 2, lines 1-15, especially line 9).

Regarding claim 6, Nova teaches binding of a protein that has a sugar chain (namely an antibody) to integrated circuit but regarding claim 6, Nova is silent how this binding is done i.e. Nova does not teach:

the binding is via the sugar chain, and recording specific information characteristic of the sugar chain of the protein.

Regarding claim 6, Geng et al. teach binding of glycopeptides via the sugar chain (see page 295 section 2.2 where synthesis of lectin columns using two different lectins (con A and Bandeiraea simplicifolia (BS-II)) is taught, and recording specific information characteristic of the sugar chain of the protein (see whole article specially see abstract where they state "the types of glycoproteins analyzed were (1) N-type glycoproteins of known primary structure, (2) N-type glycoproteins of unknown structure, and (3) O-type

glycoproteins glycosylated with a single N-acetylglucosamine. Also see page 297-298 section 3.1 the analytical protocol where selective binding of glycopeptide fragment by immobilization on different lectin columns provides specific information characteristic of the sugar chain of the protein. They state “Con A has high affinity for N-type hybrid and high mannose oligosaccharides, slightly lower affinity for complex diantennary oligosaccharides, and virtually no affinity for complex N-type tri-and tetraantenary-oligosaccharides. It is ideal for selecting glycopeptides from digests of N-type glycoproteins----------The other type of immobilized lectin examined in these studies was of narrow selectivity, generally targeting a single type of oligosaccharide----BS-II shows high selectivity for N-acetylglucosamine (GLcNAc) derivatized oligosaccharides”. Thus Geng et al. teach binding via the sugar chain and recording specific information characteristic of the sugar chain of the protein).

Any binding taught by the prior art inherently will be either by direct or indirect binding. (see claim interpretation above). Thus Geng et al. teach wherein the form of binding between the protein and the LSI is :

(i) direct binding ; or

(ii) indirect binding

Geng et al. teaches wherein a substrate mediates binding of the protein to the LSI (see page 295 section 2.2 where silica based supports is taught that mediates binding of the protein). Geng et al. also teaches wherein the substrate is silicon denatured polymer (see page 295 section 2.2 where APS silica, NAS-PAA silica is taught as silicon denatured polymer). Therefore by teaching indirect binding mediated

by silicon denatured polymer Geng et al teach indirect binding that is mediated by a substrate selected from the group consisting of cellulose vinyl acetate, α-cyanoacrylate, silicon denatured polymer, epoxy resin, and calcium sulfate.

Regarding claim 12, Geng et al. teaches wherein the form of binding between the protein and the LSI is direct binding (See claim interpretation above. Any binding taught by the prior art inherently will be either by direct or indirect binding. (see claim interpretation above). Thus Geng et al. teach wherein the form of binding between the protein and the LSI is direct binding).

Regarding claim 13, Geng et al. teaches wherein the form of binding between the protein and the LSI is indirect binding that is mediated by a substrate selected from the group consisting of cellulose vinyl acetate, α-cyanoacrylate, silicon denatured polymer, epoxy resin, and calcium sulfate (see page 295 section 2.2 where silica based supports are taught that mediates binding of the protein). Geng et al. also teaches wherein the substrate is silicon denatured polymer (see page 295 section 2.2 where APS silica, NAS-PAA silica is taught as silicon denatured polymer). Therefore by teaching indirect binding mediated by silicon denatured polymer Geng et al teach wherein the form of binding between the protein and the LSI is indirect binding that is mediated by a substrate selected from the group consisting of cellulose vinyl acetate, α-cyanoacrylate, silicon denatured polymer, epoxy resin, and calcium sulfate.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the different lectins (sugars) taught by Geng et al.

(see page 294 par. 2) to bind the glycoproteins via the sugar chain to the integrated circuits taught by Nova.

The motivation to do so is expressly provided by Hirabayashi et al. (see tilte- "Glycome project: concept, strategy and preliminary application to *C. elegans"* and also see whole article). Hirabayashi et al. state "Considering that all living organisms consist of cells covered with an abundance of such diverse carbohydrate chains reflecting various cell types and states, it should be more emphasized that these recognition events do occur at the cell level.----In other words, these glycans are regarded as functional substances , or "bar codes" to identify various cell types. In this context, analysis of protein glycosylation is a critical issue for proteomics as an important post-translational modification. Glycans have the potential to exert astronomical figures of structural diversity with a relatively small number of component saccharides, since they can create, many linkage isomers and branching types----If glycans are really important as a third class of bioinformative macromolcules, next to nucleic acids and proteins, it is essential to collect broad information about glycans under the concept of "glycome" , which refers to the entire set of glycans in one organism". (see page 295 par.1 to page 296 par. 2). Then they go on to present for the first time a basic strategy for glycomics, which targets glycoproteins. In the section 2 strategy and methodology they point out "It is important to consider which lectin should be used for isolation of glycoproteins" (see page 296 last par.).

Thus one of ordinary skill knows why its important to use different lectins to bind different glycoproteins it one wants to get a complete picture of the glycome information.

This provides the motivation to one of ordinary skill to modify the Nova device to use larger integrated circuits since Nova expressly notes “Based on current semiconductor integrated circuit fabrication process capabilities, in a preferred embodiment the finished chip on which all of the listed components are integrated is on the order of 1 mm.times.1 mm [.about.40 mils.times.40 mils], with a memory capacity of 1024 bits. Greater memory capacity, where needed, and smaller chips, however, will be preferred. The chip may be larger to accommodate more memory if desired, or may be smaller as design rules permit smaller transistors and higher device densities (see column 21, lines 8-16).”

Akram teaches that “It may, however, be desirable to design and fabricate a semiconductor wafer having various integrated circuits and other semiconductor devices thereon, each of which may be of a different size. For example, in radio-frequency ID (RFID) applications, a battery, chip and antenna could be incorporated into the same wafer such that all semiconductor devices of an RFID electronic device are fabricated from a single semiconductor wafer. Alternatively, memory dice of different capacities, for example, 4, 16 and 64 megabyte DRAMs, might be fabricated on a single wafer to maximize the use of silicon "real estate" and reduce thiefage or waste of material near the periphery of the almost-circular (but for the flat) wafer (see column 2, lines 1-13).”

An ordinary practitioner, motivated by Nova to utilize different integrated circuits with greater memory capacity where needed, would have been motivated to use the

RFID devices of Akram with 64 megabytes when performing the method on complex samples where the number of variants exceeds 320 million.

Geng et al. teach "Glycans have the potential to exert astronomical figures of structural diversity with a relatively small number of component saccharides, since they can create, many linkage isomers and branching types" (see above). Proteins have 20 amino acids and potentially each of the those amino acids could be modified by these saccharides which in which in turn can be branched.

Therefore to accommodate all the possibilities the ordinary practitioner would therefore be motivated to utilize the RFID device of Akram in the method of Nova when the glycans to be analyzed are so varied in order to permit analysis of all of the possibilities.

Conclusion

10. All claims under consideration 6, 12 and 13 are rejected over prior art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUCHIRA PANDE whose telephone number is (571)272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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